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Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

The attached application for patent term extension of U.S. Patent No. 6,156,067 was filed on July 1, 2009, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, BRYAN®cervical disc system (PMA No. P060023), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved.¹ Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

¹The filing of the application on July 1, 2009, was timely, given the NDA approval date of May 12, 2000. Applicant, however, misidentified at section 4 on page 2 of the application the last day the application may be submitted as July 4, 2009, pursuant to 37 C.F.R. § 1.740(a)(5), however, that date is day 54 in the sixty-day period of section 156(d)(1). Under both 35 U.S.C. § 156(d)(1) and 37 C.F.R. § 1.720(f), a PTE applicant has sixty days to submit a PTE application, with the first day of that sixty-day period beginning on the FDA approval date. The absolute deadline for filing the present PTE Application is thus July 10, 2009, or sixty days from May 12, 2009, starting the count of the sixty-day period on May 12, 2009. The Federal Circuit in *Unimed, Inc. v. Quigg*, 12 USPQ2d 1644, 1646, made clear that "section 156(d)(1) admits of no other meaning than that the sixty-day period begins on the FDA approval date."

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

A handwritten signature in cursive script, reading "Mary C. Till", is written over a horizontal line.

Mary C. Till

Legal Advisor

Office of Patent Legal Administration

Office of the Deputy Commissioner
for Patent Examination Policy

cc: William R. Richter
Medtronic Spinal & Biologics
2600 Sofamor Danek Drive
Memphis, TN 38132